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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,841	11/17/2000	Roger Briesewitz	STAN-130	8223

24353 7590 02/25/2003

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/18/6841

Applicant(s)

Brosenitz et al

Examiner

Kaff

Group Art Unit

651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 11/6/02
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-17, 19-32 + 51-66 is/are pending in the application.
- Of the above claim(s) 1-15 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 16, 17, 19-32 + 51-66 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

The amendment of 11/6/02 amended claims 16, 23 and 28, canceled claims 18 and 33-50, and added new claims 51-66.

Claims 1-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Claims examined on the merits are 16, 17, 19-32 and 51-66.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10                   ***Claim Rejections - 35 USC § 112***

Claims 16, 17, 19-32 and 51-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15       The claims are unclear as to the relationship of the free drug control in the last line of claims 16, 17, 23, 28, 51, 57 and 62 to the free drug control that comprises the drug previously required. It is suggested that "a drug control" in the last line be changed to -- the drug control --.

20                   ***Claim Rejections - 35 USC § 103***

Claims 16, 17, 19-32 and 51-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nygren et al (WO 91/01743) and Pouletty et al (5,843,440).

25       The claims are drawn to modulating a pharmacokinetic property by administering a bifunctional molecule of less than 5000 daltons molecular

weight consisting of a drug and a pharmacokinetic modulating moiety which may be jointed by a linker.

Nygren et al disclose extending the half-life of a biologically active protein or peptide such as a drug by binding the drug to a polypeptide fragment capable of binding to a serum protein.

Pouletty et al disclose modulating pharmacokinetics with a bifunctional reagent that is a conjugate of a binding member specific for a blood-borne target agent such as a drug (col 3, line 11) and a binding member specific for a long-lived blood associated entity (col 1, lines 40-49). The conjugates find therapeutic use by reducing effective concentration of free drug, modulating volume distribution of the drug, targeting the drug to sites of enhanced immune response or facilitating drug clearance from the blood stream (abstract and col 2, lines 23-260).

It would have been obvious to use a small-molecule drug when using a conjugate containing a drug as suggested by Nygren et al and Pouletty et al since small molecule drugs are conventionally used for treatments. Modulating a pharmacokinetic property such as half-life of the drug and volume distribution of the drug would have been obvious from Nygren et al and Pouletty et al. Modulating half-life and volume distribution of a drug would have inherently modulated hepatic first-pass metabolism as in claims 28 and 62. The use of a linker as in claims 51-66 would have been a matter of obvious choice since linkers well known for forming conjugates.

While the 132 Declaration has removed Briesewitz et al as a reference, the invention is still considered obvious over Nygren et al and Pouletty et al for reasons set forth above.

Applicant's amendment necessitated the new ground(s) of rejection  
5 presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**  
See MPEP § 706.07(a). Applicant is reminded of the extension of time  
policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set  
to expire THREE MONTHS from the mailing date of this action. In the  
10 event a first reply is filed within TWO MONTHS of the mailing date of  
this final action and the advisory action is not mailed until after the  
end of the THREE-MONTH shortened statutory period, then the shortened  
statutory period will expire on the date the advisory action is mailed,  
and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from  
15 the mailing date of the advisory action. In no event, however, will the  
statutory period for reply expire later than SIX MONTHS from the date of  
this final action.

Any inquiry concerning this communication or earlier communications  
from the examiner should be directed to David M. Naff whose telephone  
20 number is (703) 308-0520. The examiner can normally be reached on  
Monday-Thursday and every other Friday from about 8:30 AM to about 6:00  
PM.

If attempts to reach the examiner by telephone are unsuccessful, a  
message can be left on voice mail.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or  
5 (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DMN  
2/24/03

  
DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 12651